SANTA CLARA VALLEY WATER DISTRICT

Feasibility Investigation for a Small Scale Production of Bottled District Water

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Santa Clara Valley Water District

MEMORANDUM

FC 14A (06-28-93)

TO: Distribution

FROM: Jeff Micko

SUBJECT: Small Scale Production of Bottled Water

DATE: May 12, 1999

The General Manager requested an investigation of the possibility of bottling district water for distribution in our cafeteria and at district meetings versus using water bottled from other companies. This feasibility study includes an overview of the issues associated with bottling water, the institutional framework, and a comparison of alternatives for bottling District treated water on a small scale. The approximate cost of this study was $1,500 which was charged to the treated water cost center.

The District could provide a bottled water product at a relatively low price. For the projected demand, bottling under contract with an existing plant would be more cost effective than constructing an in house facility. The estimated cost for 7,000 one half liter bottles is $4,600 or $.66 per bottle.

The District could not directly bottle it's treated water. Post treatment would be required to meet State standards for total trihalomethanes. Because the cost of providing bottled water is relatively insignificant the ultimate decision should be made based upon public relations and political considerations.

Senior Civil Engineer

cc. w/attachment

S. Williams, M Klemencic, W. Wadlow, K. Whitman, T. Morse, J. Sutcliff, H. Hasse, F. Maitski, S. Oblansky

TP625M52 1999c.1

SANTA CLARA VALLEY WATER DISTRICT

Feasibility Investigation
for a
Small Scale Production of Bottled District Water

Prepared by

Jeffrey A. Micko Senior Engineer

Under the direction of

Jack Sutcliffe
Facilities Engineering Unit Manager

Marc Klemencic
Operations & Maintenance Group Manager

March 1999

SANTA CLARA VALLEY WATER DISTRICT
LIBRARY
5750 ALMADEN EXPRESSWAY
SAN JOSE, CALIFORNIA 95118

DISTRICT BOARD OF DIRECTORS

Rosemary Kamei	District 1	Gregory A. Zlotnick	District 5
Tony Estremera	District 2	Joe Judge	At Large
Robert W. Gross	District 3	Sig Sanchez	At Large
Larry Wilson, Chair	District 4		

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Project Initiation

The General Manager has requested investigation of the possibility of bottling district water for distribution in our cafeteria and at district meetings versus using water bottled from other companies. This feasibility study includes an overview of the issues associated with bottling water, the institutional framework, and a comparison of alternatives for bottling District treated water on a small scale. The approximate cost of this study was $1,500 which was charged to the treated water cost center.

Summary

The District could provide a bottled water product at a relatively low price. For the projected demand, bottling under contract with an existing plant would be more cost effective than constructing an in house facility. The estimated cost for 7,000 one half liter bottles is $4,600 or $.66 per bottle.

The District could not directly bottle it's treated water. Post treatment would be required to meet State standards for total trihalomethanes. Because the cost of providing bottled water is relatively insignificant the ultimate decision should be made based upon public relations and political considerations.

Background

Bottled Water at the District

In the past a policy was adopted not to sell or serve bottled water at the District (Appendix 4). This was presumably a demonstration of confidence in the quality of the Districts drinking water product. The policy was reversed when some employees requested that other products with lower concentrations of suspected carcinogens be made available.

The District has bottled water in the past. The public information office obtained all materials and arranged for staff to fill water at the districts water treatment plants. These were very small scale one time efforts.

An evaluation was conducted to determine the feasibility of providing a very high quality bottled water for distribution to consumers in lieu of modifying District treatment plants to conform with the new regulations of the Safe Water Drinking Act (Appendix 5). This study concluded that high cost, regulatory obstacles, and public acceptance issues limited the feasibility of such a scheme.

Bottled Water at other Districts

Bottled water production is being or has been considered by other water districts in California. The city of Sacramento concluded that a commercial water bottling operation would not be feasible. Marin County Water District is near implementation of a commercial water bottling operation whereby the proceeds would be committed to watershed protection and restoration. East Bay Municipal Water District is currently investigating the feasibility of bottling water. Metropolitan Water District of Southern California has had their water bottled under contract, but has no current bottling program.

Projected Demand

Projected demand reflects use of bottled water at meetings, for community events, and cafeteria sales. Demand estimates are based on interviews with cafeteria and Public Information Staff. Estimated demands were increased assuming some novelty purchasing would occur. Projected annual demand is 7,000 bottles per year. Demand calculations are shown in Table 1.

Table 1. Projected Annual Demand

Demand Category	Estimating Parameters	Estimated Annual Demand
Meetings	200 Working Days x 10 bottles per day	2,000
Community Events	12 Events per year X 250 bottles per event	3,000
Cafeteria Sales	200 Working Days X 10 bottles per day	2,000
Total		7,000

Liability/risk

Risk and liability is similar in nature to that which the District assumes as a drinking water supplier. Bottled water production adds another layer regulatory authority. Failure to comply will regulations will result in regulatory action. As with any food establishment, the State may perform unannounced spot inspections.

Institutional Framework

Bottled water is fully regulated at the federal, state and industry levels. Regulations pertain to water quality, labeling, monitoring and testing, facility construction and processing methods. State regulations require acquisition of a license. State regulations for total THM are ten times more stringent than the EPA drinking water standard. Text of appropriate Sections of Code are included in Appendix 2.

State Regulations

California laws pertaining to bottled water are included in the Health and Safety Code and the Administrative Code. The State of California has adopted Federal Bottled Water Quality Standards with some exceptions. Most notably the State standard for total THM in bottled water is 10 ppb compared to 100 ppb for drinking water.

Federal Regulations

There are extensive and specific FDA requirements that must be met. Federal Bottled Water Quality Standards are listed in *Title 21, Code of Federal Regulations, Section 165.110(b) formerly 103.35* Good manufacturing practices for processing, bottling, holding, and shipping of bottled water are proscribed in *Processing and Bottling of Bottled Drinking Water, Title 21, CFR, Part 129* and in *Current Good Manufacturing Practice in Manufacturing, Packing, or holding Human Food Products, Title 21, CFR, Part 110.*

Alternatives

Alternatives considered for bottling water include on site bottling or off-site bottling. Providing post treatment would be necessary to meet the State TTHM standard. The cost estimates for these alternatives are shown in Appendix 1.

On site bottling

The majority of costs associated with on site bottling would be related to setting up a bottling facility. Cost would include establishing a designated area to house the bottling facility and purchasing and setting up the equipment. The bottling facility would be subject to all federal and state regulations. Arrangements would be necessary for the purchase of bottles and labels. A license fee of about $1,000 may be required by the State (Appendix 3). District personnel would require training to operate the facility. Annual costs would include operations and maintenance and an annual license fee.

Equipment

To meet the projected annual production of 7,000 bottles, a small scale or table top operation would be appropriate. Components of the small bottling line may include a rinser, filler, labeler, and a capper. The production rate is approximately 8 bottles per minute. The estimated cost of equipment for a simple, small scale table top operation is $12,000. Using an ozone generator and contactor from the pilot facility would reduce project costs. If a new ozone generator and contactor are required the costs would increase to $26,000. The estimated unit cost for on sit bottling with existing and new ozone equipment would be $1.43 and $1.62 per bottle respectively. This includes set up labor, operation & maintenance and other material costs.

Location

The bottling facility must be enclosed in a sanitary environment. The Rinconada Water Treatment Plant has areas which could house a small facility with minimal modifications.

Staffing

The small bottling plant would require two operators. The plant would run at about 8 bottles per minute or 480 bottles per hour. Annual demand would require 2 days of production. Annual maintenance, laboratory testing and reporting was assumed to require 16 hours.

Contract bottling

Bottling could be accomplished by contracting with an existing bottling plant. The district could ship it's treated water via truck to a contractor for bottling. The contractor can bottle the Districts treated water directly or post treat the water prior to bottling. Typical post treatment would include reverse osmosis, activated carbon filtration and ozonization. The District would provide label design and contract for label production. The estimated unit cost is $0.66 per bottle. For approximately $4,600 the district could acquire 300 cases (7,200 units) of one half liter bottles filled with post treated District water within 4-6 weeks.

Appendix 1

Cost Estimates

Contract Bottling Alternative

Labor Cost	80	$/hr
Annual Production	7200	Bottles/year
Total Capital Cost	0	$

Annual Costs

			District Labor Costs			
Item	Unit	Materials $	Unit hrs/unit	Staff Hrs hrs/yr	Labor $	Total $
Bottling	0.21	$1,515		0	$0	$1,515
Lables	0.09	$658		4	$320	$978
Water Truck		$750		2	$160	$910
Shipping & Handling		$600		8	$640	$1,240
Annualized Capital Cost					$0	$0
Total Annual Cost		$3,523			$1,120	$4,643
Total Cost per Bottle						$0.66

BOTWAT.WK4

On Site Bottling Alternative A (use exinting ozone systems)

Labor Cost	80	$/hr
Annual Production	7000	Bottles/year

Capital Costs

Rinser	$1,450
Filler	$5,625
Capper	$1,125
Labeler	$4,375
Ozone Equipment	$0
Installation & Training	$10,000
Total Capital Cost	$22,575

Annual Costs

			Labor Costs			
Item	Unit	Materials $	Unit hrs/unit	Staff Hrs hrs/yr	Labor $	Total $
Bottles & Caps	0.1	$700		12	$960	$1,660
Lables	0.09	$640		8	$640	$1,280
Production			0.002	31	$2,489	$2,489
Handling				8	$640	$640
Total Annual Production						$6,069
Annual Maintenance				16	$1,280	$1,280
Annualized Capital Cost						$2,258
License Fees						$425
Total Annual Cost						$10,032
Total Cost per Bottle						$1.43

On Site Bottling Alternative B (Purchase Ozone Equipment)

Labor Cost	80	$/hr
Annual Production	7000	Bottles/year

Capital Costs

Rinser	$1,450
Filler	$5,625
Capper	$1,125
Labeler	$4,375
Ozone Equipment	$13,000
Installation & Training	$10,000
Total Capital Cost	$35,575

Annual Costs

			Labor Costs			
Item	Unit	Materials $	Unit hrs/unit	Staff Hrs hrs/yr	Labor $	Total $
Bottles & Caps	0.1	$700		12	$960	$1,660
Lables	0.09	$640		8	$640	$1,280
Production			0.002	31	$2,489	$2,489
Handling				8	$640	$640
Total Annual Production						$6,069
Annual Maintenance				16	$1,280	$1,280
Annualized Capital Cost						$3,558
License Fees						$425
Total Annual Cost						$11,332
Total Cost per Bottle						$1.62

MEPCO
LABEL SYSTEMS
29 NORTH AURORA ST.
STOCKTON, CA 95202
(209) 946-0201
FAX: (209) 946-0164
E-MAIL: *mepcoart@worldnet.att.net*

QUOTATION

16071

TO Jeff Miko
(408) 265-2607 x2548
fax (408) 264-8427

Date 2/11/99

LABEL SIZE 2 1/8 (ACROSS WEB) x 7 3/4 (ALONG WEB)

Poly prop / clear (MATERIAL)

DIECUT ☐ # R570
Circle ☐ Square ☐ Oval ☐ Rectangle ☐ Other ☐
BUTT CUT ☐ #

☐ Pin Feed (E.D.P.)
☐ Perforated #
☐ Pull Tab
☐ Face Slit
☐ Back Slit
☐ Machine Applied

ADHESIVE Cold

Colors

☒ Lamination
☐ UV Coating ☐ Lacquer

REVERSE PRINT / PMS#

1) / PMS#
2) / PMS#
3) / PMS#
4) / PMS#
5) / PMS#
6) / PMS#

Label Description	Qty.	Price/M 2 color	4 color
Water label	5M	74.08	91^{43}
	10M	54^{48}	65^{65}
	25M	42^{75}	50^{18}

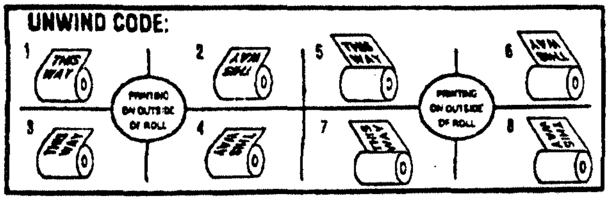
PACKAGED

☐ SHEETED ☒ ROLL

Labels Per Box
Labels Per Roll 1M
Labels Per Stack
Core Size 3"

☐ Plastic Wrap ☐ FAN FOLD ☐ Dispenser Box

UNWIND CODE:



ADDITIONAL CHARGES

Plate Changes: $8.00 each plate
Color Changes: $25.00 per color
Plate Charges: $25.00 each plate
Art Charges: $50.00 per hour
Color Match: $25.00 per color
Tooling:
Rush Charge
**Rush Fees may apply on orders due less than 10 working days.*

NOTE: Tooling cost 50% of actual cost. If customer elects to store die at their location, the remaining cost will be invoiced.
No color change, color match and plate change charges on orders exceeding 50M per item.
No plate or art charges on existing labels if order quanity of new label is 10M or more per item and sample of existing label is provided
All above charges will apply unless otherwise specified.

SHIP TIME: 3 to 4 weeks after proof approval. Repeat orders 10 working days from order entry.

TERMS: Accounts are C.O.D. until approval of credit. Net 30 following credit approval. F.O.B. Stockton, CA

Prices valid for 3 weeks from quote date. Labels must be requoted after 3 weeks.

CONDITIONS: All products are sold with the understanding that the purchaser will determine the suitability of the material for the purpose of which they are purchased. Labels will be considered defective only if errors have been made by MEPCO. Liability for defective product is limited to the price charged for the product. To receive replacement labels, the customer must notify MEPCO within 30 days after the order has been received.

BY INDUSTRY STANDARDS, ALL SHIPMENTS +/-10% OF QUANTITIES ORDERED CONSTITUTE A COMPLETED ORDER.

Prices are subject to approval by Corporate Office, Stockton, CA.

Thank you for the opportunity to quote

Sales Representative

MEPCO LABEL SYSTEMS

Special Instructions for Computer Art:

MEPCO strongly recommends using Adobe Illustrator to create artwork. If you use other programs to create artwork there may be additional art charges to produce a proof or to generate negatives.

- Other programs you may use (there may be additional art charges):
  - QuarkXPress
  - Macromedia Freehand
  - Adobe Pagemaker
  - Adobe Photoshop (for Images)

  Please include:
  all placed files (EPS, TIFF, etc)
  & all font styles
  (Suitcase and all Postcript font files used.)

- PC format artwork (there may be additional art charges).
  Artwork created on PC format will have to be converted to Macintosh format.
  We suggest the following before sending your file to us:

If you created artwork on a PC in:	We suggest:
Adobe Illustrator	--Save files as Macintosh Illustrator EPS files.
QuarkXPress	--Works fine in opening PC QuarkXPress files.
Macromedia Freehand	--Save as Macintosh EPS files.
Adobe Pagemaker	--Export as an EPS and also supply original file.
Corel Draw	--Save as Macintosh EPS file. If possible save as an Adobe Illustrator EPS file. If you send the Corel Draw file itself we will not be able to convert it to a usable form.

Since PC format fonts are not compatible with the Macintosh format, fonts need to be converted to outlines if possible. If you can't convert to outline as in QuarkXPress, please specify the Macintosh font you want us to use on your artwork.

- If there are (PLACED OR IMPORTED IMAGES) in your file the original must be supplied as a separate file (no exceptions). If they are PICT or Photoshop Images please save as the current version of Photoshop EPS for Macintosh. If the placed or imported images are vector files (created in drawing programs e.g., Adobe Illustrator) please save as the current version of Adobe Illustrator EPS files.

General Guidelines for artwork supplied:

- Do not place any traps on your work (we will do it for you).
- Gradients may be used, however, our printing process does not allow screens to fade to 0%.
- All gradient screens should be made to the minimum of 2% not to 0%. e.g., (100% to 2%).
- Color scans should be CMYK saved as TIFF, EPS or Photoshop files.
- Resolution of four color process scanned images should be 300 Dots Per Inch (DPI) at 100%.
- Line art images should be scanned at 1200 dpi at 100%.
- Image size should be the actual size used or larger.
- Fonts used in your artwork must be included. If in PC format, you will have to specify the Macintosh font desired. (PC format fonts are not compatible with the Macintosh platform.)
  - Fonts must be Macintosh compatible.
  - Include all styles (Bold, Italic, Regular.etc), screen fonts (Suitcase File) and printer fonts (Postcript File).
  - Do not use type styles (Italic, Bold, Bold Italic, etc.) unless you include these files.
  - Do not create text in Photoshop.
- Files may be sent on Zip Disk 3.5" (100MB), 3.5" diskette, Syquest 5.25" cartridge (44 or 88MB), Syquest 3.5" (270MB), or via E mail (mepco.art@worldnet.att.net).
- If you want to compress your files, please use Stuffit, Diskdoubler or be sure it's self-extracting.

revision 5/18/98

MACHINERY FOR THE BOTTLING INDUSTRY

SMB

TECHNIK, Inc.

Larry Langbehn
Sales & Marketing
5400 Alpine Road
Santa Rosa, CA 95404
USA
Tel: (707) 539-3826
Fax: (707) 538-4502

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Gert Transier
President
Boveristrasse 40
D-68309 Mannheim
Germany
Tel: (06 21) 73 70 01
Fax: (06 21) 73 70 04

February 15, 1999

Mr. Jeff Micko
SCVWD
5750 Almaden Expy
San Jose, CA 952118

Tel: (757) 495-4725
Fax: (408) 264-7427
e-mail: jeffmick@scvwd.dst.ca.us

Mr. Micko:

Thank you for your inquiry regarding a small water bottling line.

There are two proposal following. The first is your request for table top, semi-automatic bottling equipment to fill between 7 and 10 bpm of 0.5 liter PET bottles. This equipment is operated by placing 2 bottles in the filler and pressing a button to start the filling cycle. While the filler is cycling, caps are placed on the top of the 2 previous fills and tightened using a torqueing tool. This tool, basically, is an air wrench with a head that accommodates most any common plastic screw cap. The labeler is also a table top model that operates by placing a bottle between two closely spaced horizontal rollers. The button is pressed and the machine dispenses one pressure sensitive label on the bottle and stops.

The second line is a fully automatic line of about 50 bpm of 0.5 liter. I'm including it simply for your information. The line speed is limited by the filler. It's a simple in-line filler that can be made larger (faster) by attaching more in-line heads. The size quoted is a 12 head which is the largest practical machine of this type. The price difference for a smaller machine relative to the total line price doesn't justify anything lower in speed. It can be run at any speed desired to fit the availability of labor to operate the line.

Both the semi and fully automatic bottling lines can be adjusted to fill a variety of bottle sizes. The largest container which you will be able to fill on either line is a 1 gallon container. It can do as small at 8 oz.

Still water bottling lines typically sterilize the product by ozone injection into a product holding tank just prior to the filler. Please let us know if you would like us to supply this equipment.

For the fully automatic line, there are 2 labeler options shown. One option is a PVC over-sleever and the other is a pressure sensitive labeler.

The proposed equipment is manufactured by GMC corporation of Temecula, California, with the exception of the Over-Sleever which is manufactured by Marburg corporation.

Please call if you would like any further assistance.

Sincerely,

Larry Langbehn

Larry Langbehn
SMB Technik, Inc.

Water bottling line, 8 bpm x 0.5 liter, semi automatic

Rinser	
2 inverted spouts, timed rinse, 2 fluids allowable.	$1,450
Filler	
Two head, table top model, reciprocating filling heads	$5,625
Capper	
Hand held, variable air pressure, cap torqueing head	$1,125
Labeler	
Table top, pressure sensitive, single label dispenser up to full wrap	$4,375

This semi automatic equipment will require 2 people to operate it at maximum speed determined by the filler.

Water bottling line, 50 bpm x 0.5 liter, fully automatic

Feed table	
All stainless steel 48" table	
Variable speed control	
110 VAC electrics	
Solid welded support braces	$ 3,652
Filler	
All stainless steel 12 valve circulating pressure filler	
Rated speed: 50 bpm of a 0.5 liter fill	
Auto bottle indexing	
8 oz. - 1 gallon bottle sizes	$20,217

Options

8 valve filler capable of 34 bpm x 0.5 liter	Deduct $3,000
12 valve counter-pressure filler for carbonated water	Add $7,748

(A counter pressure filler can be also be used for still water.)

Capper

Stainless steel, 4 quill capper

Rater speed: 80 bpm
Magnetic clutch (positive torque) connection
Electric height control
Placed over conveyor
Bulk hopper for sport caps $17,687

Labeler option #1

Over-Sleever plus shrink tunnel
Stainless steel construction
Single head, stop action placement of plastic over cap
Separate shrink tunnel $17,400

Options

Change parts for additional cap types $8,500

Labeler option #2

Pressure Sensitive
Stainless steel
Adjustments for different bottles, no change parts required
Vacuum belt, label leading

Model Little Ruby
Single label up to full wrap $13,500
Model Starfire
Single wrap around label or front/back labeling $17,739

Accumulation table
Stainless steel 48"
Variable speed control
110 VAC electrics $ 3,130

Conveyor
Stainless steel
Varidrive speed control
Sanitary adjustable legs, 4.5' x 10'
Straight line configuration $3,360

"U" shaped configuration	$11,232

Terms

- 50% down
- Balance of 50% after inspection at manufacturer and prior to shipment.
- Prices are "ex works" the factory of manufacture in Temecula, California. Crating and shipping expenses are in addition to the purchase price.

Installation and training

Installation and training by GMC factory trained technician is required in order for the warranty to by valid. Technician costs, at standard company rates, are in addition to the purchase price.

Appendix 2

LAWS AND REGULATIONS

Relating to

BOTTLED WATER

and

Vended Water

LAWS AND REGULATIONS

Relating to

BOTTLED WATER

and

VENDED WATER

Excerpts from the
CALIFORNIA HEALTH AND SAFETY CODE

the
CALIFORNIA ADMINISTRATIVE CODE

the
U.S. Pharmacopeia

and the
CODE OF FEDERAL REGULATIONS

STATE OF CALIFORNIA
DEPARTMENT OF HEALTH SERVICES
FOOD AND DRUG BRANCH (MS-357)
P.O. Box 942732
601 N. 7th Street
SACRAMENTO, CA 94234-7320

[Revised 2/24/98, A:\wt_law1.98]

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BOTTLED, VENDED, HAULED, AND PROCESSED WATER
CALIFORNIA HEALTH AND SAFETY CODE
SECTIONS 111070 - 111195

111070 [old 26591]. (a) "Bottled water," means any water which is placed in a sealed container at a water-bottling plant to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. Bottled water shall not include water packaged with the approval of the department for use in a public emergency.

(b) "Vended water" means any water that is dispensed by a water-vending machine, retail water facility, or water from a private water source, or other water as defined in Section 111170 which is not placed by a bottler in sealed containers, and which is dispensed by a water-vending machine, retail water facility, water hauler, or any other person or facility for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. "Vended water," does not include water from a public water system which has not undergone additional treatment. Water sold without further treatment is not "vended water" and shall be labeled in accordance with paragraph (10) of subdivision (a) of Section 111170.

(c) "Water-bottling plant" means any facility in which bottled water is produced.

(d) A "water-vending machine" means any self-service device which, upon insertion of a coin, coins, or token, or upon receipt of payment by any other means, dispenses a unit volume of water to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans.

(e) "Water hauler," means any person who hauls water in bulk by any means of transportation if the water is to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans.

"In bulk," as used in this subdivision, means containers having capacities of 250 gallons or greater.

(f) "Retail water facility" means any commercial establishment where vended water is sold, and placed in customer's containers, or placed in containers sold or given to customers who come to the establishment to obtain water.

(g) "Private water source," means a privately owned source of water, other than a public water system, which is used for bottled or vended water and meets the requirements of an approved source for bottled water as defined in Section 129.3 of Title 21 of the Code of Federal Regulations.

(h) "Bottled water distributor" means any person, other than an employee or representative of a bottled water plant, who delivers bottled water directly to customers.

111075 [26591.1]. (a) Any person who processes, packages, distributes, transfers, or stores bottled water or vended water shall comply with the good manufacturing practices described in Part 129 of Title 21 of the Code of Federal Regulations.

(b) Prior to bottling or vending water, the water shall be subjected to filtration and effective germicidal treatment by ozone, ultraviolet, carbon dioxide, or an equivalent disinfection process approved by the department, except that the requirements for filtration and germicidal treatment shall not apply to mineral water as defined in and from a source that is subject to the council directive of the European Economic Community pertaining to natural mineral waters, dated July 15, 1980, or that is subject to any other natural mineral water standard in the country of origin which prohibits filtration and germicidal treatment, so long as both of the following conditions are met:

(1) The source and product are certified by the responsible authority in the country of origin as complying with microbiological standards at least equal to the standards of this article.

(2) The product complies with microbiological standards of this article.

(c) Bottled or vended water which originates from a surface water source which is not protected from surface contamination shall be subjected to ozonation, filtration, or another effective process which removes or destroys the cysts of the parasite Giardia lamblia. For the purposes of this section, a spring house, catchment basin, storage tank, or bore hole adjacent to a natural spring water source as defined in paragraphs (3) and (8) of subdivision (e) of Section 26594, is not a surface water source.

(d) Ollas or other water-holding dispensers, both refrigerated and nonrefrigerated, water-vending machines, and water dispensers in retail water facilities, shall be examined for cleanliness each time they are serviced by the distributor, bottler, retail water facility, or water-vending machine operator. When necessary, these dispensers shall be sanitized according to the methods described in Part 129 of Title 21 of the Code of Federal Regulations.

(e) Sanitary operations, equipment procedures, and process controls used in the treatment, storage, transport, or dispensing of water at a retail water facility shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivisions (a) to (c), inclusive, of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), and (h) of Section 129.80.

(f) Sanitary operations, equipment, procedures, and process controls used in the treatment, storage, transfer, transport, or dispensing of water by water haulers, shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivisions (a) and (b) of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), and (h) of Section 129.89.

(g) The design and construction of wells, bore holes, catchment basins, spring houses, storage tanks, or other water-contact equipment used by private water sources shall comply with the requirements of the local regulatory authority. Sanitary operations, equipment procedures, and transfer controls used in the treatment, storage, transfer, or dispensing of water by private water source operators shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivision (a) of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), (g), and (h) of Section 129.80.

(h) Bottled water may be processed through lines used also for other food products under the following conditions:

(1) Process lines, including storage tanks and associated equipment, shall be used exclusively for the production of bottled water, except for filling equipment, which may be used also for filling other food products.

(2) Before being used for the bottling of water, filling equipment which is designed to be cleaned in-place and which is used for filling other food products shall be thoroughly cleansed and sanitized in-place in accordance with the manufacturer's specifications and in compliance with Section 129.80 of Title 21 of the Code of Federal Regulations and the supplementary procedures that follow in paragraphs (3) to (7), inclusive, of this section.

(3) Immediately following completion of filling operations for any other food product other than water, the filler shall be thoroughly rinsed internally and externally with potable water.

(4) In accordance with filler manufacturer's instructions, any parts which are not designed to be cleaned in-place shall be disassembled and removed. All of these parts shall be cleansed and sanitized prior to reassembly using appropriate cleansing and sanitizing procedures, as specified in subdivisions (c) and (d) of Section 129.80 of Title 21 of the Code of Federal Regulations.

(5) All surfaces of the filler which do not contact food products shall be cleaned manually so as to render all surfaces clean and free of any residues.

(6) The filler shall be prepared and all appropriate connections made in accordance with the filler manufacturer's instructions to place the filler in the clean-in-place mode. The following procedures shall be followed:

(A) An alkaline cleaning solution of appropriate strength shall be recirculated through the filler to provide effective cleaning of all product contact surfaces, with a minimum recirculation time of 20 minutes at a temperature between 140 and 170 degrees fahrenheit.

(B) The cleaning solution shall be drained and followed with a potable water rinse-to-drain for the removal of all residual cleaner alkalinity. This step may be supplemented by the application of an acidified rinse prior to the potable water rinse in order to neutralize any residual alkalinity on product contact surfaces.

(7) Following reassembly of all parts to place the filler into the product mode and just prior to bottling water, the filler shall be sanitized in-place in accordance with procedures specified in subdivision (d) of Section 129.80 of Title 21 of the Code of Federal Regulations.

(8) Any alternate cleaning, rinsing, or sanitizing operations or processes not described in this section shall be approved in writing by the department.

(i) Bottled water and bulk waters sold at retail shall not contact equipment, lines, tanks, or vehicles used for processing, packaging, holding, or hauling of any nonfood product.

111080 [26591.2]. The quality standard requirements for bottled water and vended water, including mineral water, shall include all standards prescribed by Section 103.35 of Subpart B of Part 103 of Title 21 of the Code of Federal Regulations, except that water labeled as mineral water shall exceed 500 milligrams per liter of total dissolved solids and may exceed the quality standards for chloride, copper, manganese, iron, sulfate, and zinc prescribed in Section 103.35 of Title 21 of the Code of Federal Regulations. The department may develop additional standards for chloride, copper, manganese, iron, sulfate, or zinc in mineral water that the department determines are reasonably necessary to protect the public health. In addition, bottled water and vended water, when bottled, shall comply with the following quality standards and any additional quality standards adopted by regulation which the department determines are reasonably necessary to protect the public health:

(a) Bottled water and vended water shall meet all maximum contaminant levels set for public drinking water that the department determines, after public comment, are necessary or appropriate so that bottled water may present no adverse effect on public health. New or revised maximum contaminant levels or monitoring provisions adopted for bottled water by the United States Food and Drug Administration under the federal Food, Drug and Cosmetic Act that are more stringent than the state requirements for bottled water are incorporated into this chapter and are effective on the date established by the federal provisions unless otherwise established by regulations of the department.

(b) Bottled and vended water shall not exceed 10 parts per billion of total trihalomethanes or five parts per billion of lead unless the department establishes a lower level by regulation.

(c) Bottled and vended water shall contain no chemicals in concentrations which the United States Food and Drug Administration or the state department has determined may have an adverse effect on public health.

(d) Mineral water producers which bottle 5,000 gallons, or less, per week shall have until February 1, 1990, to comply with the quality standards for bottled water pursuant to this paragraph.

Mineral water producers may present to the state department data on consumption of mineral water and the health effects of inorganic elements which may be present as listed in the bottled water quality standards prescribed by Section 103.35 of Subpart B of Part 103 of Title 21 of the Code of Federal Regulations.

111085 [26591.3]. Polycarbonate resins manufactured after January 1, 1988, and intended for use in fabricating containers for water products defined in this article shall not contain in excess of three parts per million residual methylene chloride or in excess of 200 parts per million residual monochlorobenzene unless the department establishes a lower level by regulation. For the purpose of monitoring compliance with this section, the concentration of methylene chloride and monochlorobenzene shall not exceed one part per billion in water. "Polycarbonate resins" means the substances defined by Section 177.1580 of Title 21 of the Code of Federal Regulations except as modified by this section.

111090 [26591.4]. Any owner or operator of a water-vending machine or other device from which any operator or customer dispenses vended water shall comply with the following standards of design, construction and sanitation and any additional standards adopted by regulation which the department determines are reasonably necessary to protect the public health. The water-vending machines or devices shall do all of the following:

(a) Comply with the construction and performance standards established by the department or by an independent authority approved by the department.

(b) Be designed and constructed to permit easy cleaning and maintenance of all exterior and interior surfaces.

(c) Have all parts and surfaces which come into contact with the water constructed of approved, corrosive-resistant and nonabsorbent material capable of withstanding repeated cleaning and sanitizing treatment.

(d) Have a recessed or guarded corrosion-resistant dispensing spout.

(e) Be designed so that all treatment of the vended water by distillation, ion exchange, filtration, ultraviolet light, reverse osmosis, mineral addition, or any other acceptable process is done in an effective manner.

(f) Have an effective system of handling drip, spillage, and overflow of water.

(g) Have a backflow prevention device approved by the department for all connections with the water supply.

(h) Dispense water disinfected by ultraviolet light or other method approved by the department prior to delivery into the customer's container.

(i) Be equipped with monitoring devices designed to shutdown operation of the machine when the disinfection unit fails to function, or shall be monitored daily at startup and manually shutdown whenever the unit fails to function.

(j) Be equipped with a self-closing, tight-fitting door on the vending compartment, or enclosing the vending spout to protect the vending spout when the water-vending machine is not in use. As an alternative, water-vending machines or other water-dispensing devices may be enclosed in a room with tight-fitting walls, ceilings, and one of the following: a self-closing door, an effective air screen device, or an alternative effective device approved by the department.

(k) Comply with the American Water Works Association (AWWA) specifications for granular activated carbon if used in the treatment of potable water (AWWA B604-74).

(l) Be maintained in a clean and sanitary condition, free from dirt and vermin.

(m) Use a state approved and regulated public water supply or private water source.

(n) Be located in an area that can be maintained in a clean condition and in a manner that avoids insect and rodent harborage.

(o) Be equipped with monitoring devices designed to shut down the labeled purified water delivery system if treatment of water by the machine does not result in a total dissolved solids content of less than 10 milligrams per liter in the purified water. Alternatively, machines shall be monitored daily at startup and manually shutdown whenever the total dissolved solids content exceeds 10 milligrams per liter in the purified water.

111095 [26592]. It shall be unlawful to operate a bottled plant water plant, water-vending machine, retail water facility, or private water source in violation of the minimum health standards of this article.

111100 [26592.1]. It is unlawful for any person to operate a water vending machine in this state which does not satisfy the minimum standards prescribed by this article for the design, construction, and sanitation of water-vending machines.

111105 [26592.2]. The department, upon the request of a local health officer, may authorize the local health officer to implement and enforce those provisions of this article which relate to water-vending machines, retail water facilities, and water haulers under the terms and conditions specified by the department.

111110 [26592.3]. No water-vending machine shall be used in this state which does not at least satisfy the minimum standards adopted by the department.

111115 [26592.4]. The department shall require that each water-vending machine, retail water treatment plant, water hauler vehicle and facility, and private water source be maintained in a clean and sanitary condition at all times.

111120 [26593]. (a) No person shall operate a water-bottling plant, a private water source, or be a bottled water distributor in this state except pursuant to a license issued by the department. If a person has a valid water-bottling plant license issued by the department, additional license fees for a private water source operator, a retail water facility, a water hauler, or a bottled water distributor based and operating at the same address, shall not be required.

(b) No person shall own or operate a water-vending machine or a retail water facility or be a water hauler, except pursuant to a license issued by the department or to a permit issued by a local health department.

(c) It shall be unlawful for any person to bottle, collect, treat, hold, distribute, haul, vend, or sell bottled water, vended water, operate a retail water facility, or operate a private water source without the license as required by this article. Any bottled water or vended water dispensed by a retail water facility or a private water source that is not licensed in compliance with this article is misbranded and may be embargoed pursuant to subdivision (e) of Section 111120.

(d) It shall be unlawful for a water bottler, distributor, vendor, retail water facility operator, or private water source operator to sell or otherwise distribute water that is adulterated, as defined in Section 110445, 110545, 110560, or 110565, or that is misbranded as defined in Article 6 (commencing with Section 110660) of Chapter 5.

(e) For the purposes of enforcing this section, water may be embargoed pursuant to Section 111860 in its immediate container, well, spring, spring vault, holding tank, water hauling vehicle, retail water treatment system, spigot, or pipe if there is reasonable cause to believe that it is adulterated.

(f) Any retail water facility, water vendor, or water hauler which violates this article may be subjected to the same penalty and enforcement procedure provided for violation of this article by a water bottling facility.

111125 [26593.1]. No bottled water produced in an out-of-state bottling plant shall be sold or distributed within this state unless either the out-of-state bottler or the distributor shall have first obtained a bottler's or distributor's license.

111130 [26593.2]. (a) The department shall charge and collect a fee for each license application submitted in accordance with the fee schedule in Table 1, which shall be an amount reasonably necessary to produce sufficient revenue to enforce the provisions of this article. The fees collected shall be adjusted annually as required by Section 100425. New applicants for a water bottling plant license shall pay Category 2 fees for the first license year.

(b) The water-bottling plant and bottled water distributor categories shall be determined by dividing by 52 the number of gallons produced or shipped into California during the previous year. If the result is an average of 5,000 gallons or less per week, the firm is Category 1. If the average exceeds 5,000 gallons per week, the firm is Category 2.

Table 1
License Fees for 1998*

License Class	Annual Fee*
Water-Bottling Plant	
Category 1	$325.80
Category 2	919.63
Water-Vending Machine	10.75
Water Hauler	325.80
Retail Water Facility	325.80
Private Water Source Operator	325.80
Bottled Water Distributor	325.80

* *Revised to show the 1998 fees*

(c) The owners or operators of each water-bottling plant, retail water facility, private water source, each water hauler in California and bottlers or distributors of water bottled out-of-state shall make application for a license on forms provided by the department. Applications and license fees shall be submitted for each calendar year.

(d) Each water-vending machine owner or operator shall make application each calendar year for a license for all machines on forms provided by the department. A decal or [illegible] provided by the department indicating a license fee has been paid shall be affixed in a prominent place to each water-vending machine in service.

111135 [26593.3]. The department may deny any license application or revoke or suspend any license issued for cause. The department shall inform the person of any denial, revocation, or suspension in writing, stating with particularity reasons for the denial, revocation, or suspension.

"Cause," as used in this section, means a violation of any provision of this chapter or any regulation adopted pursuant thereto.

111140 [26593.4]. The department shall charge and collect a fee for each department evaluation required to issue a new license for a water-vending machine model or a retail water facility to determine compliance with standards established by this article. The fee shall be three hundred dollars ($300) and shall be adjusted annually as required by Section 100425.

111145 [26593.5]. (a) The department shall require each bottler, distributor, or vendor of bottled water, each owner or operator of any water-vending machine, each water hauler, each retail water facility operator, each private water source operator, and each applicant for a license, to test for all substances necessary to establish conformance to standards adopted pursuant to Section 111080 at the times and frequencies the department may reasonably establish.

(b) Each product dispensed by a water-vending machine or a retail water facility shall be sampled and analyzed for coliform bacteria at least once every six months. The analysis shall be submitted to the department indicating whether the water is pure and wholesome. Analysis of vended water or water from retail water facilities shall be submitted to the local health officers if the local health officers are authorized by the department pursuant to subdivision (b) of Section 111105.

(c) Purified waters from retail water facilities shall be analyzed by the operator for dissolved solids by conductivity measurement not less frequently than once every seven days.

(d) Purified water from vending machines shall be analyzed by the operator for the dissolved solids by conductivity measurement each time the vending machine is serviced.

111150 [26593.6]. (a) All sources of bottled water, vended water, and water dispensed by a retail water facility shall be monitored annually for the presence of volatile organic compounds of potential public health concern, as specified by the United States Environmental Protection Agency in Tables 2 and 14 contained in Volume 50 of the Federal Register on pages 46904, 46923, and 46924 on November 13, 1985, or as reasonably specified by the department as a condition of licensure.

(b) In lieu of source water monitoring required by this section, a water bottler, water vendor, or a retail water facility may document that the source monitoring required by this section is conducted by another entity approved by the department, or may comply with the treatment requirements of subdivision (c).

(c) Detection in the source water of a volatile organic compound, except trihalomethanes, for which source monitoring is required pursuant to this section shall be followed immediately by a program of periodic monitoring by the water bottler, water vendor, or retail water facility to confirm the presence or absence in the source water of the volatile organic compound. If the volatile organic compound is confirmed to be present in the source water it shall be treated using granular activated carbon treatment or an equivalent treatment operated in accordance with good manufacturing practices as provided in Section 129.80 of Title 21 of the Code of Federal Regulations until the time that the concentration of the volatile organic compound does not exceed either one part per billion, or any United States Environmental Protection Agency or United States Food and Drug Administration level for drinking water, or a maximum contaminant level established by the department for bottled water.

(d) The department may exempt any water bottler, water vendor, or retail water facility from the monitoring requirements of this section for any source based on a showing satisfactory to the department that the source (1) does not contain the volatile organic compound for which monitoring is required and (2) is not vulnerable to contamination by the volatile organic compound because for surface water sources the compounds are not applied, manufactured, stored, disposed or shipped upstream, and for groundwater sources, the compounds are not applied, manufactured, stored, disposed, or shipped in the groundwater recharge basin.

111155 [26593.7]. Notwithstanding any other provisions of this article, the department may require any bottler, distributor, or vendor of bottled water, any owner or operator of a water-vending machine, any water hauler, any retail water facility operator, any private water source operator, or any applicant for a license to test and submit results to the department for any substance, including organic chemical contaminants, at any time which the department believes the substance may be present in the water source and threaten the public health.

111160 [26593.8]. (a) Upon a determination by the department that a particular water source is subject to potential contamination, the department shall notify the bottler, distributor, or vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator of the specific contaminants or class of contaminants which pose a potential health risk.

(b) Within 90 days after notification by the department, the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator shall conduct an analysis of the water source and submit the results of the analysis to the department.

(c) If evidence of contamination is found, the department may, by order, require the bottler, distributor, vendor of bottled water, or the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator to conduct a source and product water analysis for the contaminants of concern in accordance with conditions specified by the department. The water analysis shall be conducted and reported on an annual basis, unless the department finds that reasonable action requires either more frequent or less frequent analysis.

(d) The department may, by order, require the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator to reduce or eliminate the concentration of any chemical which the department determines may have an adverse effect on public health. Until an enforceable standard has been established for a chemical which may have an adverse effect on human health, the department may require treatment techniques to reduce the concentration of the contaminants which require treatment, in the department's judgment, to prevent known or anticipated adverse effects on the health of persons. The treatment system shall be designed to meet criteria designated by the department or by an independent authority approved by the department.

(e) The department may grant variances from the requirements of subdivision (d), if the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator demonstrates either of the following:

(1) That the prescribed treatment technique is not necessary to protect the health of consumers because its water source is not subject to, nor is it likely to be subject to, significant chemical contamination.

(2) An alternative treatment technique is at least as efficient in lowering the level of contaminants to be controlled.

111165 [26593.9]. All testing of bottled water, bottled water sources, water distributed by water haulers, water from retail water facility, and water from vending machines shall be done by laboratories approved by the department, laboratories certified by the United States Environmental Protection Agency, laboratories certified by the primary enforcement authority in states which have been granted primacy by the United States Environmental Protection Agency, or laboratories certified (accredited) by a third-party organization acceptable to a primacy state.

111170 [26594]. (a) Labeling and advertising of bottled water and vended water shall conform with the provisions of this section and Chapter 4 (commencing with Section 110290) of Division 21 and Part 101 of Title 21 of the Code of Federal Regulations.

(b) Each container of bottled water sold in this state, each water-vending machine, and each container provided by retail water facilities located in this state shall be clearly labeled in an easily readable format. Retail water facilities which do not provide labeled containers shall post, in a location readily visible to consumers, a sign conveying required label information.

(c) Water-vending machines, retail water facilities, and private water sources which sell water at retail shall display in a position clearly visible to customers the following information:

(1) The name and address of the operator.

(2) The fact that the water is obtained from an approved public water supply or licensed private water source.

(3) A statement describing the treatment process used.

(4) If no treatment process is utilized a statement to that effect.

(5) A telephone number that may be called for further information, service, or complaints.

(d) Bottled water may be labeled "drinking water," notwithstanding the source or characteristics of the water, only if it is processed pursuant to the Food and Drug Administration Good Manufacturing Practices contained in Section 103.35 and Parts 110 and 129 of Title 21 of the Code of Federal Regulations, Sections 12235 to 12285, inclusive, of Title 17 of the California Code of Regulations, and any other requirements established by the department pursuant to Sections 111145, 111150, and 111155. Any vended water and any water from a retail water facility may be labeled "drinking water," notwithstanding the source or characteristics of the water, only if it is processed pursuant to Article 10 (commencing with Section 114200) of Chapter 4 of Division 22 and any other requirements established by the department pursuant to Sections 111145, 111150, and 111155.

111175 [26594.1]. (a) In addition to the requirements of Section 111170, if a bottler, distributor, water hauler, retail water facility operator, or vending machine operator provides information in the labeling or advertising stating or implying that this water is of a specific water type (for example, "spring water") or treated in a specific manner (for example, "purified"), the type or treatment shall be clearly labeled in an easily readable format. In order to be so labeled, the source or treatment shall conform to the following criteria:

(1) "Artesian well water" means water from a well tapping an aquifer in which the water level will stand above the bottom of the confining bed of the aquifer, and in which the hydraulic

pressure of the water in the aquifer is greater than the force of gravity. Artesian well water shall not be altered by the addition or deletion of minerals or by blending it with water from a nonartesian well water source, except that artesian well water may be filtered and shall be treated with ozone or an equivalent disinfection process.

(2) "Fluoridated water" means water containing naturally occurring or added fluoride. The label shall specify whether fluoride is naturally occurring or is added. Any water which meets the designation of this paragraph shall contain not less than 1.0 milligrams per liter fluoridization and otherwise comply with the Food and Drug Administration quality standards set forth in Section 103.35(d) (2) of Title 21 of the Code of Federal Regulations.

(3) "Mineral water" means bottled water or vended water containing more than 500 milligrams per liter of total dissolved solids and originating entirely from an underground source, which may be a well, artesian well, or spring. Bottled or vended mineral water may be derived from a natural orifice or from a bore hole adjacent to the natural orifice. If it is derived from a natural orifice or from a bore hole adjacent to the natural orifice, the water shall be from the same underground stratum and be of the same quality and composition as the water derived from the natural orifice without external force. Mineral water may not be altered by the addition or deletion of minerals or by blending it with water from a nonmineral water source, except that mineral water may be filtered and shall be treated with ozone or an equivalent disinfection process approved by the department and shall be treated to reduce the concentrations of any naturally occurring substance which exceeds the bottled water safety standards established by the department. Mineral water may be collected and transported by pipes, tunnels, trucks, or similar devices. Any water which meets the criteria of this paragraph may also be labeled "natural mineral water."

(A) Mineral water which contains carbon dioxide as it emerges from the source and is bottled directly with its entrapped gas, or from which the gas is mechanically separated and later reintroduced into the water at the time of bottling shall be labeled "naturally carbonated" or "naturally sparkling."

(B) Mineral water which contains carbon dioxide, other than that naturally occurring in the source product, shall be labeled with the words "carbonation added" or "carbon dioxide added" when the carbonation is obtained from a natural or manufactured source.

(4) "Mineralized water" means bottled or vended water which meets the requirements of "mineral water" except that the water contains added minerals.

(5) "Natural water" means bottled or vended spring, artesian well, or well water which is unmodified by mineral addition or deletion, except "natural water" may be filtered and shall be sanitized with ozone or an equivalent disinfection process and treated to reduce the concentration of any substance which exceeds safety standards established by the department.

(6) "Naturally sparkling water" means bottled water or vended water with a carbon dioxide content from the same source as the water. "Sparkling," "carbonated," or "carbonation added" means bottled water or vended water which contains carbon dioxide.

(7) "Purified water" means water produced by distillation, deionization, reverse osmosis, or other method meeting the definition of purified water in the 21st edition of the United States Pharmacopeia. Water which meets the designation of this paragraph, and is vaporized, then condensed, may be labeled "distilled water."

(8) ~~"Spring water" means water which issues by natural forces out of the earth at a particular place. Bottled or vended spring water may be derived from the natural orifice or from a bore hole adjacent to the natural orifice. If it is derived from the natural orifice by external force or from a bore hole adjacent to the natural orifice, the water shall be from the same underground stratum and be of the same quality and composition as the water derived from the natural orifice without external force. Spring water may not be altered by the addition or deletion of minerals or by blending it with water from a nonspring water source, except that spring water may be filtered and shall be treated with ozone or an equivalent disinfection process. Spring water may be collected and transported by pipes, tunnels, trucks, or similar devices.~~

> *[NOTE: The federal court in Sacramento ruled on September 22, 1997 (Case # CIV.No.S-97-1048 EJD/DAD) that the state standard of identity for "spring water" was preempted by the federal standards.]*

Federal Standard of identity for "spring water" [21CFR Section 165.110(a)(2)(vi)]:

> The name of water derived from an underground formation from which water flows naturally to the surface of the earth may be "spring water." Spring water shall be collected only at the spring or through a bore hole tapping the underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified. Spring water collected with the use of an external force shall be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the bore hole and the natural spring., and shall have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring's natural orifice. Plants shall demonstrate, on request, to appropriate regulatory officials, using a hydrogeologically valid method, that an appropriate hydraulic connection exists between the natural orifice of the spring and the bore hole.

(9) "Well water" means water from a hole bored into the ground which taps the water of an aquifer, except that well water may be filtered and shall be treated with ozone or an equivalent disinfection process. Well water may not be altered by the addition or deletion of minerals or by blending it with water from a nonwell water source.

(10) Notwithstanding any other provision of this section, water from a public water system which is unprocessed by the bottler or vendor shall be labeled as "unprocessed public drinking water."

111180 [26594.2]. Except as provided in Section 111080, any bottled water or vended water, the quality of which is below the quality required by this article, shall be labeled with a statement of substandard quality, as prescribed by Section 103.35 of Title 21 of the Code of Federal Regulations.

111185 [26594.3]. Any bottler, distributor, vendor of bottled water, or owner or operator of any water-vending machine or retail water facility, whose corporate name or trademark contains the words "spring" or "springs," or any derivative of either of these words, or "well," "artesian well," or "natural" shall label each bottle or vending machine with the source of the water in typeface at least equal to the size of the typeface of the corporate name or trademark, if the source of the bottled or vended water is different from the source stated in the corporate name or trademark. Retail water facilities which do not provide labeled containers shall post, in a location readily visible to consumers, a sign conveying required label information.

111190 [26594.4]. (a) A bottled water, as defined in Section 111170, with natural or added carbonation, may be prepared with added flavors, extracts, essences, or fruit juice concentrates derived from a spice or fruit and comprising less than 1 percent by weight of the final product.

The final product shall contain no sweeteners, or additives other than the flavors, extracts, essences, or fruit juice concentrates and carbon dioxide and shall be designated on labels and in advertising as follows:

(1) The common or usual name of the characterizing flavor shall accompany the designation of the bottled water product type as defined in subdivision (b) of Section 111170.

(2) The product may be designated as "natural" only if it meets the requirements for the designation as defined in paragraphs (5) and (6) of subdivision (b) of Section 111170, and naturally derived flavors, extracts, or essences are used.

(b) Products labeled pursuant to this section shall comply with all other provisions of this article. Products with one type or one source of bottled water that are labeled pursuant to this section shall not be blended with water that is not bottled water or that is of another bottled water type.

111195 [26594.5]. The department, prior to issuing a license, shall review all labels prepared pursuant to this article, and may require any changes in order to comply with the provisions of this article.

SANITATION REQUIREMENTS FOR VENDING MACHINES
CALIFORNIA HEALTH AND SAFETY CODE
CALIFORNIA UNIFORM RETAIL FOOD FACILITIES LAW
SECTIONS 114200 - 114245

114200 [old 27650]. This article governs sanitation requirements for vending machines as defined in this chapter.

114205 [27651] . Each vending machine or machine location shall have posted in a prominent place a sign indicating the owner's name, address, and telephone number.

114210 [27652]. All food shall be stored and packaged in clean, protected containers, and handled, transported, and vended in a sanitary manner. Wet storage of packaged products is prohibited.

Potentially hazardous food shall be dispensed to the consumer in the original package into which it was placed at the commissary or processing plant. Bulk potentially hazardous food is prohibited.

114215 [27653]. All food contact surfaces shall be cleaned and sanitized either in place in a machine so designed and approved or by removing from the machine and cleaning and sanitizing at an approved facility.

All food contact surfaces when removed from the machine after cleaning and sanitizing shall be protected from contamination before being returned to the machine.

A record of cleaning and sanitizing shall be maintained by the operator in each machine and shall be current for at least the past 30 days.

114220 [27654]. Single-service containers which are used in machines dispensing products in bulk, shall be obtained in sanitary packages, shall be stored in a clean, dry place until used, and shall be handled in a sanitary manner. The containers shall be stored in the original package until introduced into the container magazine or dispenser of the vending machine. The containers stored within the vending machine shall be protected from manual contact, dirt, vermin, and other contamination.

114225 [27655]. Each vending machine shall be located in a room, area, or space which shall minimize the potential for contamination of food. The floor area upon which vending machines are located shall be smooth, of cleanable construction, and capable of withstanding repeated washing and scrubbing.

114230 [27656]. Water used in vending machines shall be potable.

114235 [27657]. While in transit to machine locations, food, single-service containers, and equipment shall be protected from dirt, vermin, and other contamination.

114240 [27658]. On or after January 1, 1985, all vending machines shall be constructed in accordance with National Sanitation Foundation or National Automatic Merchandizing Association standards, or the equivalent thereof.

114245 [27659]. Vending machines shall meet all the requirements of Article 6 (commencing with Section 113975) and applicable sections of Article 7 (commencing with Section 113990).

FOOD SANITATION - FOOD PROCESSING ESTABLISHMENTS
CALIFORNIA HEALTH AND SAFETY CODE
SECTIONS 111950 - 112055

111950 [old 28280]. "Food," as used in this chapter, includes all articles used for food, drink, confectionery, or condiment. Whether simple or compound, and all substances and ingredients used in the preparation thereof.

111955 [28280.1]. "Food processing establishment," as used in this chapter, shall mean any room, building or place or portion thereof, maintained, used or operated for the purpose of commercially storing, packaging, making, cooking, mixing, processing, bottling, canning, packing, slaughtering or otherwise preparing or handling food except restaurants.

111960 [28281]. Every food processing establishment shall be properly lighted, drained, plumbed, and ventilated; and shall be conducted with strict regard to the influence of lighting, drainage, plumbing, and ventilation upon the health of persons therein employed, and upon the purity and wholesomeness of the food therein produced, prepared for sale, manufactured, packed, stored, kept, handled, sold, or distributed.

111965 [28282]. The floors, side walls, ceiling, furniture, receptacles, utensils, implements, and machinery of every food processing establishment shall at no time be kept in an unclean, unhealthful, or unsanitary condition.

Any of the following is deemed to be "an unclean, unhealthful, or unsanitary condition":

(a) If food in the process of manufacture, preparation, packing, storing, sale, or distribution is not securely protected from flies, dust, or dirt, and from all other foreign or injurious contamination.

(b) If refuse, dirt, and waste products subject to decomposition and fermentation incident to the manufacture, preparation, packing, storing, selling, and distributing of food, are not removed daily.

(c) If all trucks, trays, boxes, baskets, buckets, other receptacles, chutes, platforms, racks, tables, shelves, knives, saws, cleavers, and all other utensils, receptacles, and machinery used in moving, handling, cutting, chopping, mixing, canning, and all other processes employed in the preparation of food are not thoroughly cleaned daily.

(d) If the clothing of employees is unclean or if they dress, undress, or leave or store their clothing in the place where the food is produced, prepared, manufactured, packed, sold or distributed.

111970 [28282.5]. No live animal or fowl shall be kept or allowed in any establishment where food is prepared, manufactured, kept, stored, offered for sale or sold unless such establishment is exclusively devoted to the slaughter, processing and/or sale of such animal or fowl.

This section does not apply to dogs used by uniformed employees of private patrol operators and operators of a private patrol service who are licensed pursuant to Chapter 11 (commencing with Section 7500) of Division 3 of the Business and Professions Code, while such employees are acting within the course and scope of their employment as private patrolmen.

The state department may adopt rules and regulations as it determines are reasonably necessary under this section for the protection of the public health and safety.

111975 [28283]. The side walls and ceilings of every bakery, confectionery, hotel, or restaurant kitchen shall be well plastered with metal or lumber, or shall be oil painted or kept well lime washed, or otherwise kept in a good sanitary condition.

111980 [28284]. All interior woodwork of every bakery, confectionery, hotel, or restaurant kitchen shall be kept well oiled or painted with oil paint, and shall be kept washed clean with soap and water, or otherwise kept in a good sanitary condition.

111985 [28285]. Every building, room, basement, or cellar occupied or used for the preparation, manufacturer, packing, storage, sale or distribution of food shall have an impermeable floor, made of cement, or of tile laid in cement, brick, wood, or other suitable, nonabsorbent material which can be flushed and washed clean with water.

111990 [28286]. Where practicable, the doors, windows, and other openings of every food producing or distributing establishment shall be fitted with stationary or self-closing screen doors and wire window screens, of not coarser than 14 mesh wire gauze.

111995 [28287]. Every building, room, basement, or cellar occupied or used for the production, preparation, manufacture, packing, canning, sale, or distribution of food shall have convenient toilet or toilet-rooms, separate and apart from the room or rooms where the process of production, preparation, manufacture, packing, canning, selling, or distributing is conducted.

112000 [28288]. The floors of toilet-rooms shall be made of cement, or of tile laid in cement, wood, brick, or other nonabsorbent material, and shall be washed and scoured daily.

112005 [28289]. The toilets shall be furnished with separate ventilating pipes or flues discharging either into soil pipes or on the outside of the building in which they are situated.

112010 [28290]. Lavatories and washrooms shall be adjacent to toilet-rooms and shall be supplied with soap, running water, and towels, and shall be maintained in a clean and sanitary condition.

112015 [28291]. Employees and others who handle the material from which food is prepared or the finished product shall before beginning work and immediately after visiting a toilet or lavatory, wash their hands and arms thoroughly in clean water.

112020 [28292]. No employee or other person shall sit or lie upon any table, bench, trough, shelf, or other equipment which is intended for use in connection with any food manufacturing process.

112025 [28293]. No employee or other person shall expectorate or discharge any substance from his nose or mouth on the floor or interior side wall of any building, room, basement, or cellar where the production, preparation, manufacture, packing, storing, or sale of any food is conducted.

112030 [28294]. No person shall, nor shall any person be allowed to, reside or sleep in any room of a bake-shop, public dining-room, hotel or restaurant kitchen, confectionery, or other place where food is prepared, produced, manufactured, served, or sold.

112035 [28295]. No employer shall require or permit any person to work, in a food processing establishment or vehicle used for the production, preparation, manufacture, sale, or transportation of food if the person is infected with any contagious, infectious, or communicable disease which can be transmitted by the food involved.

112040 [28296]. The state department, its inspectors and agents, and all local health officers and inspectors may at all times enter any building, room, basement, cellar, or other place occupied or used, or suspected of being occupied or used, for the production, preparation, manufacture, storage, sale or distribution of food, and inspect the premises and all utensils, implements, receptacles, fixtures, furniture, and machinery used.

112045 [28297]. If upon inspection any such building, room, basement, cellar, or other place, or any vehicle, employer, employee, or other person is found to be in violation of or violating any of the provisions of this article, or if the production, preparation, manufacture, packing, storing, sale, or distribution of food is being conducted in a manner detrimental to the health of the employees or to be character or quality of the food being produced, prepared, manufactured, packed, stored, sold, distributed, or conveyed, the person making the inspection shall at once make a written report of the violation to the district attorney of the county, who shall prosecute the violator. He shall make a like report to the state department. The state department, from time to time, may publish such reports in its monthly bulletin.

112050 [28298]. Every building, room, basement, cellar, or other place or thing kept, maintained, or operated in violation of this article, and all food produced, prepared, manufactured, packed, stored, kept, sold, distributed, or transported in violation of this article, is a public nuisance dangerous to health. Any such nuisance may be abated or enjoined in an action brought for that purpose by the local or state department or may be summarily abated in the manner provided by law for the summary abatement of public nuisances dangerous to health.

112055 [28299]. The sections contained in this article are to be known as the California Food Sanitation Act.

SANITATION IN FOOD PLANTS
CALIFORNIA ADMINISTRATIVE CODE, TITLE 17
CHAPTER 5, SUBCHAPTER 2, GROUP 1
ARTICLE 7, SECTIONS 12245 - 12280

12245. General Plant Sanitation; Floors, Walls, Ceilings, Etc.

The floors, walls, ceilings, partitions, posts, doors and other parts of all preparation and processing areas shall be of such materials, construction and finish that they may be readily and thoroughly cleaned. The floors in all areas where water is used in the operation are to be so constructed and of such material as to be watertight and they shall be maintained in such condition as to stay watertight. All areas used for edible products shall be separate and distinct from those used for inedible products, such as fish meal reduction plants.

12250. Areas, Equipment, and Operations to Be Sanitary.

(a) Areas, equipment and utensils used for preparing, storing, or otherwise handling any food product and all other parts of the establishment shall be kept clean and in a sanitary condition. Areas in which any food product is prepared, processed, stored or handled, including walls, ceilings, and overhead structures of such areas, shall be kept as reasonably free from moisture as is practicable. In such areas there shall be no dripping from any source, including ceilings and overhead structures, that may contaminate the product.

(b) Equipment and utensils used for preparing, processing or otherwise handling any food product shall be of such materials and construction that they can be readily and thoroughly cleaned. Pipelines used to convey fluid or semi-fluid products shall be so constructed that they can be readily and thoroughly cleaned.

(c) Operations and procedures involving the preparation, storing or handling of any food product shall be strictly in accord with good sanitary practice.

12255. Use of Poisonous Insecticides and Rodenticides.

(a) Every practical precaution shall be taken to keep establishments free from flies, rats, mice and other vermin. If necessary, rodent-proof rooms shall be provided for materials which might become contaminated by these pests.

(b) The use of insecticides, or rodenticides, toxic to humans, in areas where any food products, not adequately protected, is being stored or handled is prohibited.

(c) Poisonous insecticides and rodenticides may be used under buildings, wharves, outbuildings, or similar places, or where adequately protected packaged products are stored; only, if adequate precautions are taken to eliminate the possibility of said poisons being accidentally spilled, or carried, by any means, to areas where these poisons are prohibited. These poisons are to be adequately protected from possible contact by children, or domestic animals, and are to be plainly and distinctly labeled for identification by adults.

12260. Empty Container Storage.

Empty cans, jars, lids, covers, barrels, drums, etc., must be clean when filled with food products.

12275. Personal Hygiene.

(a) The employees of the establishment who handle any food product shall keep their hands clean; and, after visiting the toilet room or urinals, shall wash their hands before handling any food product or implement used in the preparation of the product.

(b) Outer clothing and gloves worn by persons who handle any food product shall be clean and of material that can be readily cleaned.

(c) Such practices as spitting on the floor and using empty cans, jars, or other containers as drinking cups, or for purposes other than those originally intended, are forbidden.

(d) Care shall be taken to prevent the contamination of food products with perspiration, hair, cosmetics, medicaments and the like. Adequate head coverings must be worn by all men and women while engaged in the preparation or handling of any food product.

(e) Smoking by any person shall not be permitted while preparing or handling any food product or while handling empty cans, jars, lids, barrels, drums or other receptacles used for food products.

(f) The use of fingernail polish by any person preparing, processing, or handling any food product without gloves whereby the product might become contaminated, is prohibited.

(g) No clothing, shoes, boots, aprons, etc. shall be kept or stored in any area where any food product is prepared, processed, or handled; except, in or on facilities specifically provided for this purpose.

12280. Sanitary Facilities.

Adequate sanitary facilities and accommodations shall be furnished by every food packing establishment. Of these the following are specifically required:

(a) Dressing rooms, and toilet and urinal rooms shall be sufficient in number and conveniently located. These rooms shall be well lighted, sufficiently ventilated to insure sanitary conditions, vented to the outside, and meet all requirements as to sanitary construction and equipment. All doors entering such rooms shall be self-closing. All windows shall be screened. Such rooms shall be separate from areas in which food products are prepared, stored, or handled. The walls, ceiling, partitions, and other parts of all dressing rooms, toilet rooms, lavatory rooms and urinal rooms shall be of light color and of such construction as to be easily and adequately cleaned. Where five or more persons of both sexes are employed, separate facilities shall be provided for each sex.

(b) Sanitary washing facilities, including running hot and cold water, soap and individual towels, shall be provided, and shall be placed in or near toilet and urinal rooms and also at other places in the establishment as may be essential to insure cleanliness of all persons handling any food product.

(c) Adequate lockers or cloak rooms for all employees shall be provided and shall be kept clean and well ventilated.

(d) Toilet soil lines shall be kept separate from industrial waste lines to a point outside the buildings. Drainage from toilet bowls and urinals shall not be discharged into grease salvage basins, or into open disposal systems.

BOTTLED WATER QUALITY STANDARDS
TITLE 21, CODE OF FEDERAL REGULATIONS
SECTION 165.110(b) [old 103.35]
Effective May 13, 1996

Subpart B--Standards of Quality

165.110(b) Quality.

The standard of quality for bottled water, including water for use as an ingredient in beverages (except those described in the labeling as "water," "carbonated water," disinfected water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "sparkling water," and "tonic water"), is as follows:

(a) Definitions. (1) "Bottled water" is defined as water that is sealed in bottles or other containers and intended for human consumption. Bottled water does not include mineral water or any type of soft drink commonly known as soda water, which is made by absorbing carbon dioxide in potable water.

(2) "Trihalomethane" (THM) means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

(3) "Total Trihalomethanes" (TTHM) means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane [chloroform], dibromochloromethane, bromodichloromethane and tribromomethane [bromoform]), rounded to two significant figures.

(4) "Microbiological quality." Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), American Public Health Association, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (copies may be obtained from the American Public Health Association, 1015 11th St., N.W., Washington, DC 20005, or copy may be examined at the Office of the Federal Register, 800 North Capitol St., NW., Suite 700, Washington, DC, or at the Center for Food Safety and Applied Nutrition, 200 C St., SW., Washington, DC), meet the following standards of standards of microbiological quality:

(1) Multiple-tube fermentation method. Not more than one of the analytical units in the sample shall have a most probably number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or

(2) Membrane filter method. Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.

(c) Physical quality. Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of "Standard

Methods for the Examination of Water and Wastewater," 15th Ed. (1980), which is incorporated by reference (the availability of this incorporation by reference is given in paragraph (b)(2) of this section), meet the following standards of physical quality:

(1) The turbidity shall not exceed 5 units.

(2) The color shall not exceed 15 units.

(3) The odor shall not exceed threshold odor No. 3.

(d) Chemical quality. (1)(i) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(4)(i)(B) of this section, meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:

Substance	Concentration in Milligrams per Liter
Arsenic	0.05
Chloride	250.0
Iron	0.3
Manganese	0.05
Phenols	0.001
Sulfate	250.0
Total dissolved solids	500.
Zinc	5.0
Organics:	
Endrin (1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,41,5, 6,7,8,8a-Octa-hydro-1,4-endo,endo-5,8-dimethano naphthalene)	0.0002
Total Trihalom	0.10

(B) Analyses conducted to determine compliance with paragraph (b)(4)(i)(A) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), or "Methods for Chemical Analysis of Water and Wastes," Environmental Monitoring and Support Laboratory (EMSL), EPA-600/4-79-020, March 1983, U.S. Environmental Protection Agency (EPA), both of which are incorporated by reference in accordance with U.S.C. 552(a)and 1 CFR part 51.

(C) Analyses for organic substances shall be determined by the appropriate methods set forth below. The methods in paragraphs (b)(4)(i)(C)(1) and (C)(2) of this section are incorporated by reference in accordance with 5 U.S.C. 552(a) and CFR part 51 and are described in "Standard Methods for examination of Water and Wastewater," 15th Ed. (1980). Copies may be obtained from the American Public Health Association, 1015 Fifteenth St., NW., Washington, DC 20005, and examined at the Office of the Federal Register, 800 North Capitol St., NW., Suite 700, Washington, DC or the Center for Food Safety and Applied Nutrition, 200 C St., NW, Washington, DC. The methods in paragraphs (b)(4)(i)(C)(3) and (C)(4) are cross-referenced in 40 CFR part 141, subpart C, Appendix C.

(1) "Methods for Organochlorine Pesticides in Industrial Effluents;"

(2) "Methods for Chlorinated Phenoxy Acid Herbicides in Industrial Effluents," November 28, 1973;

(3) "Part I: The Analysis of Trihalomethanes in Finished Water by the Purge and Trap Method;" which is cross-referenced in 40 CFR part 141, subpart C, appendix C;

(4) "Part II: The Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction," Method 501.2 which is cross-referenced in 40 CFR part 151, subpart C, appendix C;

(a) Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

Annual average of maximum daily air temperatures ('F)	Fluoride concentration in milligrams per liter
53.7 and below	2.4
53.8 - 58.3	2.2
58.4 - 63.8	2.0
63.9 - 70.6	1.8
70.7 - 79.2	1.6
79.3 - 90.5	1.4

(b) Imported bottled water to which fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

(c) Bottled water packaged in the United States to which fluoride is added shall not contain fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 2

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	1.7
53.8 - 58.3	1.5
58.4 - 63.8	1.3
63.9 - 70.6	1.2
70.7 - 79.2	1.0
79.3 - 90.5	0.8

(d) Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

(e) Having consulted with EPA as required by section 410 of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has determined that bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraphs (b)(4)(III)(E) through (b)(4)(iii)(F), and (b)(4)(iii)(G) of this section, shall not contain the following chemical contaminants in excess of the concentrations specified in paragraphs (b)(4)(iii)(A) through (b)(4)(iii)(D) of this section.

(1) The allowable levels for inorganic substances are as follows:

Barium	2.0
Cadmium	0.005
Chromium	0.1
Copper	1.0
Lead	0.005
Mercury	0.002
Nitrate (N)	10 (as nitrogen)
Nitrite	1 (as nitrogen)
Total Nitrate & Nitrite	10 (as nitrogen)
Selenium	0.05

(2) The allowable levels for volatile organic chemicals (VOC's) are as follows:

Contaminant	Concentration in milligrams per liter
Benzene	0.005
Carbon tetrachloride	0.005
o-Dichlorobenzene	0.6
p-Dichlorobenzene	0.075
1,2-Dichloroethane	0.005
1,1-Dichloroethylene	0.007
Dichloroethylene	0.07
trans-1,2 Dichloroethylene	0.1
1,2-Dichloropropane	0.005
Ethylbenzene	0.7
Monochlorobenzene	0.1
Styrene	0.1
Tetrachloroethylene	0.005
Toluene	1
1,1,1-Trichloroethylene	0.20
Trichloroethylene	0.005
Vinyl chloride	0.002
Xylenes	10

(3) The allowable levels for pesticides and other synthetic organic chemicals (SOC's) are as follows:

Contaminant	Concentration in milligrams per liter
Alachlor	0.002
Atrazine	0.003
Carbofuran	0.04
Chlordane	0.002
1,2-Dibromo-3-chloropropane	0.0002
2,4-D (94-75-7)	0.07
Ethylene dibromide	0.00005
Heptachlor	0.0004
Heptachlor epoxide	0.0002
Lindane	0.0002
Methoxychlor	0.04
Pentachlorophenol	0.001
PCB's (as decachlorobiphenyl)	0.0005

Toxaphene	0.003
2,4,5-TP (Silvex)	0.05

(D) The allowable levels for certain chemicals for which EPA has established secondary maximum contaminant levels in its drinking water regulations (40 CFR part 143) are as follows:

Contaminant	Concentration in milligrams per liter
Aluminum	0.2
Silver	0.1

[Note: Please see 21 CFR Section165.110(b) and Federal Register, Volume 60, 11/23/95, Page 57076 to 57130 for more details.]

PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER
TITLE 21, CODE OF FEDERAL REGULATIONS
PART 129

Subpart A--General Provisions

129.1 Current good manufacturing practice.

The applicable criteria in Part 110 of this chapter, as well as the criteria in subsections 129.20, 129.35, 129.37, 129.40, and 129.80 shall apply in determining whether the facilities, methods, practices, and controls used in the processing, bottling, holding, and shipping of bottled drinking water are in conformance with or are operated or administered in conformity with good manufacturing practice to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions.

129.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) "Approved source" when used in reference to a plant's product water or operations water means a source of water and the water therefrom, whether it be from a spring, artesian well, drilled well, municipal water supply, or any other source, that has been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality according to applicable laws and regulations of State and local government agencies having jurisdiction. The presence in the plant of current certificates or notifications of approval from the government agency or agencies having jurisdiction constitutes approval of the source and the water supply.

(b) "Bottled drinking water" means all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(c) "Lot" means a collection of primary containers or unit packages of the same size, type, and style produced under conditions as nearly uniform as possible and designated by a common container code or marking.

(d) "Multiservice containers" means containers intended for use more than one time.

(e) "Nontoxic materials" means materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled drinking water, which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor, or bacteriological quality of the water.

(f) "Operations water' means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.

(g) "Primary container" means the immediate container in which the product water is packaged.

(h) "Product water" means processed water used by a plant for bottled drinking water.

(i) "Shall and should." "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(j) "Shipping case" means a container in which one or more primary containers of the product are held.

(k) "Single-service container" means a container intended for one time usage only.

(l) "Unit package" means a standard commercial package of bottled drinking water, which may consist of one or more containers.

Subpart B--Buildings and Facilities

129.20 Plant construction and design.

(a) The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors to protect against contamination. Conveyor openings shall not exceed the size required to permit passage of containers.

(b) If processing operations are conducted in other than a sealed system under pressure, adequate protection shall be provided to preclude contamination of the water and the system.

(c) Adequate ventilation shall be provided to minimize condensation in processing rooms, bottling rooms, and in container washing and sanitizing areas.

(d) The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room. The washing and sanitizing operation shall be positioned within the room so as to minimize any possible post-sanitizing contamination of the containers before they enter the bottling room.

(e) Rooms in which product water is handled, processed, or held or in which containers, utensils, or equipment are washed or held shall not open directly into any room used for domestic household purposes.

129.35 Sanitary facilities.

Each plant shall provide adequate sanitary facilities including, but not limited to, the following:

(a) Product water and operations water--(1) Product water. The product water supply for each plant shall be from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(2) Operations water. If different from the product water supply , the operations water supply shall be obtained from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at

all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(3) Product water and operations water from approved sources. (i) Samples of source water are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every 4 years for radiological contaminants. Additionally, source water obtained from other than a public water system is to be sampled and analyzed for microbiological contaminants at least once each week. This sampling is in addition to any performed by government agencies having jurisdiction. Records of approval of the source water by government agencies having jurisdiction and of sampling and analyses for which the plant is responsible are to be maintained on file at the plant.

(ii) Test and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum requirements set forth in Section 103.35 of this chapter.

(iii) Analysis of the samples may be performed for the plant by competent commercial laboratories.

(b) Air under pressure. Whenever air under pressure is directed at product water or a product water-contact surface, it shall be free of oil, dust, rust, excessive moisture, and extraneous materials; shall not affect the bacteriological quality of the water; and should not adversely affect the flavor, color, or odor of the water.

(c) Locker and lunchrooms. When employee locker and lunchrooms are provided, they shall be separate from plant operations and storage areas and shall be equipped with self-closing doors. The rooms shall be maintained in a clean and sanitary condition and refuse containers should be provided. Packaging or wrapping material or other processing supplies shall not be stored in locker or lunchrooms.

129.37 Sanitary operation.

(a) The product water-contact surfaces of all multiservice containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of product water shall be clean and adequately sanitized. All product water-contact surfaces shall be inspected by plant personnel as often as necessary to maintain the sanitary condition of such surfaces and to assure they are kept free of scale, evidence of oxidation, and other residue. The presence of any unsanitary condition, scale, residue, or oxidation shall be immediately remedied by adequate cleaning and sanitizing of that product water-contact surface prior to use.

(b) After cleaning, all multiservice containers, utensils, and disassembled piping and equipment shall be transported and stored in such a manner as to assure drainage and shall be protected from contamination.

(c) Single-service containers and caps or seals shall be purchased and stored in sanitary closures and kept clean therein in a clean, dry place until used. Prior to use they shall be examined, and as necessary, washed, rinsed, and sanitized and shall be handled in a sanitary manner.

(d) Filling, capping, closing, sealing, and packaging of containers shall be done in a sanitary manner so as to preclude contamination of the bottled drinking water.

Subpart C--Equipment

129.40 Equipment and procedures.

(a) Suitability. (1) All plant equipment and utensils shall be suitable for their intended use. This includes all collection and storage tanks, piping, fittings, connections, bottle washers, fillers, cappers, and other equipment which may be used to store, handle, process, package, or transport product water.

(2) All product water contact surfaces shall be constructed of nontoxic and nonabsorbant material which can be adequately cleaned and sanitized and is in compliance with section 409 of the act.

(b) Design. Storage tanks shall be of the type that can be closed to exclude all foreign matter and shall be adequately vented.

Subpart E--Production and Process Controls

129.80 Processes and controls.

(a) Treatment of product water. All treatment of product water by distillation, ion-exchanging, filtration, ultraviolet treatment, reverse osmosis, carbonation, mineral addition, or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose and in accordance with section 409 of the Federal Food, Drug, and Cosmetic Act. All such processes shall be performed in and by equipment and with substances which will not adulterate the bottled product. A record of the type and date of physical inspections of such equipment, conditions found, and the performance and effectiveness of such equipment shall be maintained by the plant. Product water samples shall be taken after processing and prior to bottling by the plant and analyzed as often as is necessary to assure uniformity and effectiveness of the processes performed by the plant. The methods of analysis shall be those approved by the government agency or agencies having jurisdiction.

(b) Containers. (1) Multiservice primary containers shall be adequately cleaned, sanitized, and inspected just prior to being filled, capped, and sealed. Containers found to be unsanitary or defective by the inspection shall be reprocessed or discarded. All multiservice primary containers shall be washed, rinsed, and sanitized by mechanical washers or by any other method giving adequate sanitary results. Mechanical washers shall be inspected as often as is necessary to assure adequate performance. Records of physical maintenance, inspections and conditions found, and performance of the mechanical washer shall be maintained by the plant.

(2) Multiservice shipping cases shall be maintained in such condition as to assure they will not contaminate the primary container or the product water. Adequate dry or wet cleaning procedures shall be performed as often as necessary to maintain the cases in satisfactory condition.

(c) Cleaning and sanitizing solutions. Cleaning and sanitizing solutions utilized by the plant shall be sampled and tested by the plant as often as is necessary to assure adequate performance in the cleaning and sanitizing operations. Records of these tests shall be maintained by the plant.

(d) Sanitizing operations. Sanitizing operations, including those performed by chemical means or by any other means such as circulation of live steam or hot water, shall be adequate to effect sanitization of the intended product water-contact surfaces and any other critical area. The plant should maintain a record of the intensity of the sanitizing agent and the time duration that the agent was in contact with the surface being sanitized. The following times and intensities shall be considered a minimum:

(1) Steam in enclosed system: At least 170` F for at least 15 minutes or at least 200` F for at least 5 minutes.

(2) Hot water in enclosed system: At least 170` F for at least 15 minutes or at least 200` F for at least 5 minutes.

(3) Chemical sanitizers shall be equivalent in bactericidal action to a 2-minute exposure of 50 parts per million of available chlorine at 57` F when used as an immersion or circulating solution. Chemical sanitizers applied as a spray or fog shall have as a minimum 100 parts per million of available chlorine at 57` F or its equivalent in bactericidal action.

(4) 0.1 part per million ozone water solution in an enclosed system for at least 5 minutes.

(5) When containers are sanitized using a substance other than one provided for in Section 178.1010 of this chapter, such substance shall be removed from the surface of the container by a rinsing procedure. The final rinse, prior to filling the container with product water, shall be performed with a disinfected water rinse free of pathogenic bacteria or by an additional sanitizing procedure equivalent in bactericidal action to that required in paragraph (d)(3) of this section.

(e) Unit package production code. Each unit package from a batch or segment of a continuous production run of bottled drinking water shall be identified by a production code. The production code shall identify a particular batch or segment of a continuous production run and the day produced. The plant shall record and maintain information as to the kind of product, volume produced, date produced, lot code used, and the distribution of the finished product to wholesale and retail outlets.

(f) Filling, capping, or sealing. During the process of filling, capping or sealing either single-service or multiservice containers, the performance of the filler, capper or sealer shall be monitored and the filled containers visually or electronically inspected to assure they are sound, properly capped or sealed, and coded and labeled. Containers which are not satisfactory shall be reprocessed or rejected. Only nontoxic containers and closures shall be used. All containers and closures shall be sampled and inspected to ascertain that they are free from contamination. At least once each 3 months, a bacteriological swab and/or rinse count should be made from at least four containers and closures selected just prior to filling and sealing. No more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms. The procedure and apparatus for these bacteriological tests shall be in conformance with those recognized by the government agency or agencies having jurisdiction. Tests shall be performed either by qualified plant personnel or a competent commercial laboratory.

(g) Compliance procedures. A quality standard for bottled drinking water, excluding mineral water, is established in Section 103.35 of this chapter. To assure that the plant's production of bottled drinking water complies with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction, the plant will analyze product samples as follows:

(1) For bacteriological purposes, take and analyze at least once a week a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product.

(2) For chemical, physical, and radiological purposes, take and analyze at least annually a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample(s) consists of primary containers of product of unit packages of product.

(3) Analyze such samples by methods approved by the government agency or agencies having jurisdiction. The plant shall maintain records of date of sampling, type of product sampled, production code, and results of the analysis.

(h) Record retention. All records required by sections 129.1, 129.20, 129.3 [illegible] 129.37, 129.40, and 129.80 shall be maintained at the plant for not less than 2 years. Plants shall also retain on file at the plant, current certificates or notifications of approval issued by the government agency or agencies approving the plant's source and supply of product water and operations water. All required documents shall be available for official review at reasonable times.

U. S. PHARMACOPEIA
PURIFIED WATER

Purified Water is water obtained by distillation, ion-exchange treatment, reverse osmosis, or other suitable process. It is prepared from water complying with the regulations of the federal Environmental Protection Agency with respect to drinking water. It contains no added substance.

NOTE--Purified Water is intended for use as an ingredient in the preparation of compendial dosage forms. Where used for sterile dosage forms, other than for parenteral administration, process the article to meet the requirements under Sterility Tests 71 , or first render the Purified Water sterile and thereafter protect it from microbial contamination. Do not use Purified Water in preparations intended for parenteral administration. For such purposes use Water for Injection, Bacteriostatic Water for Injection, or Sterile Water for Injection.

Packaging and storage--Where packaged, preserve in tight containers.

Labeling--Where packaged, label it to indicate the method of preparation.

pH 791 : between 5.0 and 7.0, determined potentiometrically in a solution prepared by the addition of 0.30 mL of saturated potassium chloride solution to 100 mL of test specimen.

Chloride--To 100 mL add 5 drops of nitric acid and 1 mL of silver nitrate TS: no opalescence is produced.

Sulfate--To 100 mL add 1 mL of barium chloride TS: no turbidity is produced.

Ammonia--To 100 mL add 2 mL of alkaline mercuric-potassium iodide TS: any yellow color produced immediately is not darker than that of a control containing 30ug of added NH_3 in High-purity Water (see under Reagents in Containers 661) [0.3 ppm].

Calcium--To 100 mL add 2 mL of ammonium oxalate TS: no turbidity is produced.

Carbon dioxide--To 25 mL add 25 mL of calcium hydroxide TS: the mixture remains clear.

Heavy metals--Adjust 40 mL of Purified Water with 1 N acetic acid to a pH of 3.0 to 4.0 (using short-range pH indicator paper), add 10 mL of freshly prepared hydrogen sulfide TS, and allow the liquid to stand for 10 minutes: the color of the liquid, when viewed downward over a white surface, is not darker than the color of a mixture of 50 mL of the same Purified Water with the same amount of 1 n acetic acid as was added to the test specimen, matched color-comparison tubes being used for the comparison.

Oxidizable substances--To 100 mL add 10 mL of 2 N sulfuric acid, and heat to boiling. Add 0.1 mL of 0.1 N potassium permanganate, and boil for 10 minutes; the pink color does not completely disappear.

Total solids--Evaporate 100 mL on a steam bath to dryness, and dry the residue at 105° for 1 hour: not more than 1 mg of residue remains (0.001%).

Bacteriological purity--It complies with the federal Environmental Protection Agency regulatic for drinking water with respect to bacteriological purity (40 CFR 141.14; 141.21).

CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD
TITLE 21, CODE OF FEDERAL REGULATIONS
PART 110

Subpart A--General Provisions

110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) "Acid foods or acidified foods" means foods that have an equilibrium pH of 4.6 or below.

(b) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) "Batter" means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) "Blanching," except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) "Critical control point" means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) "Food" means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) "Food-contact surfaces" are those surfaces that contact human food and those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

(h) "Lot" means the food produced during a period of time indicated by a specific code.

(i) "Microorganisms" means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.

(j) "Pest" refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) "Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding or human food.

(l) "Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) "Rework" means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) "Safe-moisture level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

(o) "Sanitize" means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) "Shall" is used to state mandatory requirements.

(q) "Should" is used to state recommended or advisory procedures or identify recommended equipment.

(r) "Water activity" (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B--Buildings and Facilities

110.20 Plant and grounds.

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a)(1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

110.35 Sanitary operations.

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) Substances used in cleaning and sanitizing; storage of toxic materials. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive airflow systems).

(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(10 Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their

hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) Rubbish and official disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C--Equipment

110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart E--Production and Process Controls

110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) Raw materials and other ingredients. (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by

purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) Manufacturing operations. (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45° F (7.2° C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140° F (60° C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable

microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined that found hot to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in { 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the a_w of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to law-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart G--Defect Action Levels

110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. S.W., Washington, DC 20204.

Appendix 3

Procedures for Obtaining an in State Water Bottling License

CALIFORNIA DEPARTMENT OF HEALTH SERVICES
FOOD AND DRUG BRANCH
WATER LICENSING DESK (MS-357)
P.O. BOX 942732
SACRAMENTO, CA 94234-7320
(916) 323-4774

PROCEDURES FOR OBTAINING AN IN-STATE WATER BOTTLING PLANT LICENSE:

California Health and Safety Code (H&SC) Section 111120 requires that a bottler obtain a license issued by the Department of Health Services' Food and Drug Branch (FDB) to operate a water-bottling plant in California. The following describes what you must do to help us issue your license as quickly as possible:

LICENSE APPLICATION

Submit a completed application form in duplicate to the address shown on the application together with the required fee, which is non-refundable. The license is valid for one calendar year and expires on December 31. The business address must be that of the bottling plant, not that of the corporate headquarters. The mailing address can be either that of the plant, corporate headquarters or the firm's branch office (the license will be mailed to the mailing address). Any incomplete and/or illegible application will be RETURNED to the applicant, which would result in a significant delay in the processing of that application.

FDB will perform an on-site inspection of the plant before issuing a license to assure that the bottling facility meets the requirements specified in Part 129 of Title 21 of the Code of Federal Regulations (21 CFR), and other state and federal laws. Please contact one of the nearest FDB offices (see the list attached) for a phone number to call for an appointment for inspection.

NOTE: ***Submit the information specified below (items 1, 2 3 and 4) in duplicate to a Food and Drug Investigator at the time of inspection of your facility.***

INFORMATION REQUIRED AT THE TIME OF INSPECTION

1. Water Source: All water sources must be identified on the application form. Only water from a licensed source or approved public drinking (or municipal) water districts can be processed for bottling.

A. If an unlicensed private well or spring source is the source of the water supply and the well or source is based and operated at the same location as the bottling plant, submit also a completed Private Water Source Operator's (PWSO) license application form in duplicate together with all required supporting documents and information as specified in the "Procedure For Obtaining A Private Water Source Operator License." The license application fee for the PWSO license may be waived pursuant to H&SC Section 111120. Please contact the Water Licensing Desk (916-323-4774) to obtain the PWSO license application form, procedures and the list of substances to be analyzed.

B. If the source is currently licensed for the sale of the particular water, provide information to that effect. The information must include name of the source owner, purchase contract, location of the source, license number of the PWSO, and telephone number of PWSO. If the source is not currently licensed and not located at the site of bottling plant, a PWSO license application must be submitted with the application fee and required documents/information as indicated in the "Procedure for Obtaining a Private Water Source Operator License".

C. If public drinking (or municipal) water is used as a source, provide the name of the Water District, address, telephone number, and a copy of the Water District's most recent chemical, physical and microbiological analysis data for the water.

2. Analytical Tests Required (If you have multiple products to be bottled at the facility, you must submit multiple sets of analysis for each product.):

- General chemical, physical, and radiological quality of water as required by the federal quality standards of bottled water and H&SC Sections 111150 and 111155 (see the attachment, Group I, II, III and V for specific substances). The test report should be valid for one year from the date of analysis.

- Bacteriological quality of water as required by the federal quality standards of bottled water (Group IV).

NOTE: All testing must be done by a California certified water laboratory [certified for the analyses performed; contact the California Environmental Laboratory Accreditation Program at (510) 540-2800 for information] or by a laboratory certified by the Unites States Environmental Protection Agency (USEPA). Testing done by a laboratory approved by the primary enforcement authority in states which have been granted primacy by the USEPA is also acceptable according to H&SC Section 111165.

3 Bottling Operation:

- Schematic site (facility) diagram;
- Schematic water treatment/bottling process diagram;
- Evidence (attach photographs) whether the facility has a separate bottling room in compliance with the requirement of 21 CFR 129.20(a);
- Indication whether the bottling room is operated in a sealed system under pressure;

- Specifications of equipment (please do not send copies of promotional material or advertisements; State on the top of the first page of each specification sheet whether the equipment has been approved for food and/or potable water use, and the approval organization);
- Sanitation procedures;
- Information on your "unit package production code" as required by 21 CFR Part 129 (We suggest that a copy of your "recall plan," which includes the production code information, be submitted);
- Information on your record keeping as required by 21 CFR Part 129 (We suggest that a copy of your "product quality control procedure," which includes the record keeping information, be submitted);
- Photographs showing the bottling equipment and facility.

4. Labels and Promotional Materials:

Submit labels, advertising and promotional materials (original; not photocopies). Typed or photo-copied labels may be submitted with prior approval of FDB only if the labels are: (1) printed or embossed directly on bottles, or (2) large labels (greater than 100 square inches in label size) printed directly on large boxes. Labels, advertising, and promotional materials must meet the requirements of H&SC Section 109875 et seq. and applicable federal regulations [including those for nutrition labeling if nutrient content or health claims are made or if nutrition information which triggers nutrition labeling is provided].

FOOD AND DRUG BRANCH OFFICES

FDB Water Licensing Desk

P.O. BOX 942732
601 North 7th Street (MS-357)
SACRAMENTO, CA 94234-7320
Telephone: (916) 323-4774; FAX (916) 322-6326

FDB Los Angeles Office

1449 West Temple Street, Room 224
Los Angeles, CA 90026
Telephone: (213) 580-5720; FAX (213) 580-5750

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY

DEPARTMENT OF HEALTH SERVICES
FOOD AND DRUG BRANCH

WATER BOTTLING PLANT LICENSE APPLICATION
(In-State or Out-of-State Bottler)

INSTRUCTIONS: A separate application SUBMITTED IN DUPLICATE is required for each place of business.

The fee for each RENEWAL or NEW application in the sum indicated below payable to the DEPARTMENT OF HEALTH SERVICES must accompany this application. Unsigned or incomplete applications cannot be processed. For **RENEWAL applications**, please indicate the license number on the top right hand corner of your check and on this application. Please submit original and duplicate applications with the appropriate fee to:

Check One Box That Applies For **1999** Application Fee:
(PCA Code 81227)
FEE for **New** WATER BOTTLING PLANT: $919.63 ( )
FEE for **Renewal**-WATER BOTTLING PLANT:
If less than 5,000 gal./week: $325.80 ( )
If more than 5,000 gal./week: $919.63 ( )

DEPARTMENT OF HEALTH SERVICES
FOOD AND DRUG BRANCH
P.O. BOX 942832
SACRAMENTO, CA 94234-0006

Type of Application; check one: In-State ( ) Out-of-State ( )

Check one: Renewal ____ New ____ Amended ____

IF RENEWAL, LICENSE NUMBER: ________ ____________________

NAME OF FIRM: ______________________________

DBA (If appropriate): ______________________________

PLACE OF BUSINESS (ACTUAL BOTTLING PLANT LOCATION) STREET/CITY/ZIP: ____________________

______________________________ Area Code/Phone: ____________

MAILING ADDRESS (if different from above) P.O. BOX/CITY/STATE/ZIP: ____________________

______________________________ Emergency Phone: ____________

PERSON RESPONSIBLE FOR OPERATIONS: ______________________________

CORRESPONDENT: ______________________________

BOTTLED WATER PRODUCTS: (CIRCLE CODE / ATTACH LABELS)

AVERAGE WEEKLY WATER GALLONAGE PRODUCTION FOR LAST YEAR **

A. Drinking
B. Distilled
C. Mineralized
D. Mineral

E. Fluoridated
F. Flavored
G. Spring
H. Artesian Well

I. Carbonated (Sparkling)
J. Purified by Deionization
K. Purified by Reverse Osmosis
L. Well (Non-artesian)):
M. Other (Describe ______________________________

** Average weekly production is determined by dividing the total number of gallons either produced in or shipped into California by 52.

LIST OF ALL PRODUCT BRAND NAMES BOTTLED AT YOUR FACILITY (ATTACH LABELS). ATTACH SEPARATELY IF MORE SPACE IS NEEDED

____________ ____________ ____________

____________ ____________ ____________

Continued on Page Two

Is your water source(s) from private water or public water? Please indicate name, address, and phone number of private water source(s) or water district. Please include the License number(s) of private water source(s).

Were any changes made from the previous application? [ ] Yes [ ] No If yes, please explain.

Type of ownership: [ ] Partnership, [ ] Association, [ ] Corporation, [ ] Individual/Sole Proprietorship, [ ] Other (Describe):

If an individual or sole proprietorship

Name of individual or sole proprietor Name of business entity (DBA)

If a partnership or other unincorporated association:

Name of each partner or member Name of the partnership or association

If a corporation:

Name of corporation Name of state of incorporation

Name and title of each corporate officer and corporate director:

The Food and Drug Branch MUST BE NOTIFIED IMMEDIATELY of any change in the above information If any changes were made, explain on a separate sheet. Under penalty of perjury, under the laws of the State of California, the person whose signature appears below, certifies and says that: (1) He/she is the applicant, or one of the applicants, or an executive officer of the applicant corporation, named in the foregoing application, duly authorized to make this application on its behalf; (2) he/she has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; (3) no person other than the applicant or applicants has any direct or indirect interest in the applicant's business to be conducted under the license for which this application is made; and (4) all supplemental statements are true and accurate.

SIGNATURE OF APPLICANT: ______________________________ DATE: ______________

PRINT NAME AND TITLE OF APPLICANT: ______________________________

Appendix 4

District Policy Relating to the Use of Bottled Water

Appendix 5

In House Analysis on Producing Bottled Water to Replace Treated Water for Drinking

Oblonsky

Santa Clara Valley Water District

MEMORANDUM

FC 14A (04-11-88)

To: Walt Wadlow

From: Frank Maitski

Subject: Bottled Water Analysis

Date: June 18, 1991

We have investigated the possibility of producing very high quality bottled water to consumers for drinking purposes in lieu of modifying District treatment plants to conform with new regulations of the Safe Drinking Water Act. If feasible, this would allow the District to treat to a high level only that portion of the supply that is consumed, and continue with the current treatment practices for non-drinking water such as landscape irrigation.

In assessing any new water source, three specific items must be considered; regulatory compliance, economics, and public acceptance. All three are discussed below.

Regulatory Compliance

We conducted an informal discussion with staff of the California Department of Health Services (DOHS) on this issue. They believe that current state law prohibits any large water agency from implementing this type of bottled water system to comply with new Safe Drinking Water Act regulations. As a domestic water supplier, all water delivered by the agency must meet all water quality standards.

The public health rationale is that some of the public (i.e. small children and visitors) would not be aware that only the bottled water was safe to drink and they would consume tap water. Also, non-drinking uses of water are also considered when developing water quality standards. Bottled water would not address the public health concern associated with aerosols that are produced when people take a shower. If the District wanted to implement a bottled water program, State law would have to be modified.

Economics

Information from the Environmental Protection Agency (EPA) indicates that the average person consumes two liters of water per day. This is slightly greater than one-half gallon per day. In discussions with bottled water suppliers, this amount is typical with what they deliver to customers in Santa Clara County; therefore, an economic analysis was developed assuming this consumption.

The current population of Santa Clara County is approximately 1.5 million people. Not all of the population receives treated water from the District; however, a large percentage probably receives at least some treated water mixed with groundwater. The economic analysis was conducted for populations of 0.75, 1.0, and 1.5

million people instead of estimating the number of people who receive some treated water. The results of the analysis are shown on the attachment.

The annualized costs are $43, $58, and $87 million for populations of 0.75, 1.0, and 1.5 million people, respectively. Capital costs range from $51 to $103 million, and annual operation and maintenance costs range from $36 to $73 million. Using this analysis, bottled water is produced and delivered to consumers at a cost of $0.31 per gallon. In contrast, Alhambra delivers 5 gallon bottles of water to individual homes at a cost to the customer of $1.50 per gallon.

The difference in the cost per gallon is attributable not only to a profit margin, but that Alhambra's cost represents the total cost to acquire, treat, and distribute the water. Also, some additional District costs are not included in this analysis. The estimate of $0.31 only represents an additional cost to treat the water with a reverse osmosis system and deliver it to consumers. The ongoing costs to acquire and treat the water through filtration and disinfection are not included.

In review of the analysis, the distribution costs far exceed the production costs. This is due to the assumption that a truck can only make one complete delivery per day. A typical truck carries only 180 5-gallon bottles, or 900 gallons, total. This requires the purchase of 520 to 1,040 trucks and the hiring of 670 to 1,370 truck drivers. If a bottled water system was ever implemented, the distribution would most likely be privatized.

Cost savings in the distribution system could probably be achieved to lower the overall cost of delivering bottled water. However, there are also other factors that would tend to increase the cost. The most important is the basic assumption that consumption is only two liters per person per day (0.52 gpd). If DOHS would agree to allow this system, they would probably require a greater volume to be delivered to include not only drinking, but cooking and washwater, as well. If the volume was increased, it would have a direct, linear effect on the costs since no real economy of scale exists for reverse osmosis and truck delivered water.

Cost items not included in this study are general administrative and engineering costs to implement the system including management of the truck driver staff, environmental mitigation, reverse osmosis brine and bottle washwater disposal, annual replacement of lost or stolen bottles, and operation and maintenance of bottle washing. All of these could provide a significant cost increase.

Public Acceptance

Acceptance of a bottled water system could be difficult to obtain from not only the general public, but also the water retailers. The message that would be sent to the public is that tap water was unfit to drink. This problem could be exacerbated if DOHS requires a small sign on each tap stating that the water was not safe to drink, similiar to the signs required for reclaimed water distribution systems. A very positive public information campaign would be necessary.

A major public acceptance issue is environmental compliance with siting, and brine and washwater disposal. The most likely site to treat the water is at the Rinconada Water Treatment Plant. The citizens of Los Gatos would probably not allow the large volume of traffic to occur that would be necessary to implement this idea. In terms of water conservation, the brine and washwater produced would not be consistent with the District's water conservation message, and it probably would not be accepted by the water pollution control facilities.

Other acceptance issues include possible unfair competition complaints from bottled water suppliers, pressures to unionize the labor force of truck drivers, and the impact on water supply during emergencies such as earthquakes. These would all have to be explored more fully.

It is difficult to recommend that a bottled water system be implemented to comply with new Safe Drinking Water Act regulations. The annual costs to distribute the water would be very high and major obstacles exist in regulatory compliance and public acceptance. The issue of modifying state (and probably federal) law to allow this concept would probably be extremely controversial and probably not in the best interest of the public.

original signed by

Senior Civil Engineer
Surface Water Protection

cc: R. James, L. Cournoyer, F. Maitski, S. Oblonsky, Read, File

Attachments